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(54) **Measurement of a physical parameter of body tissue**

(57) The "tissue specific temperature" of body tissue is measured and compared with a previously established standard to quantify susceptibility of the tissue to an abnormality such as cancer. For carrying out this method a brassiere 1 carries a number of temperature responsive sensors 2 which pass information to a central processor 5 which receives also signals representative of ambient and other body temperature from sensors 4 and 3, respectively. All these measurements are then used to evaluate the "tissue specific temperature".

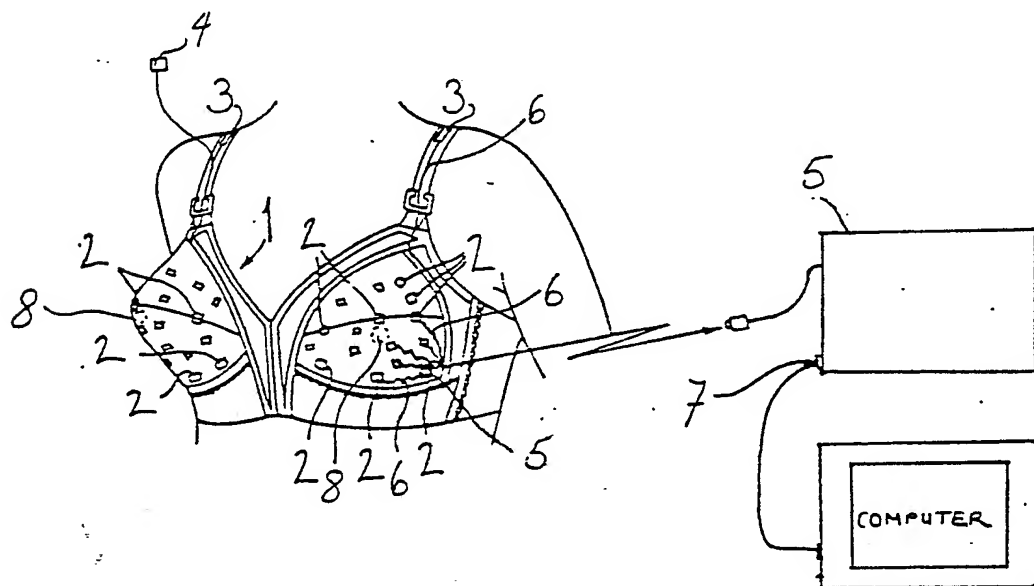


Fig. 1

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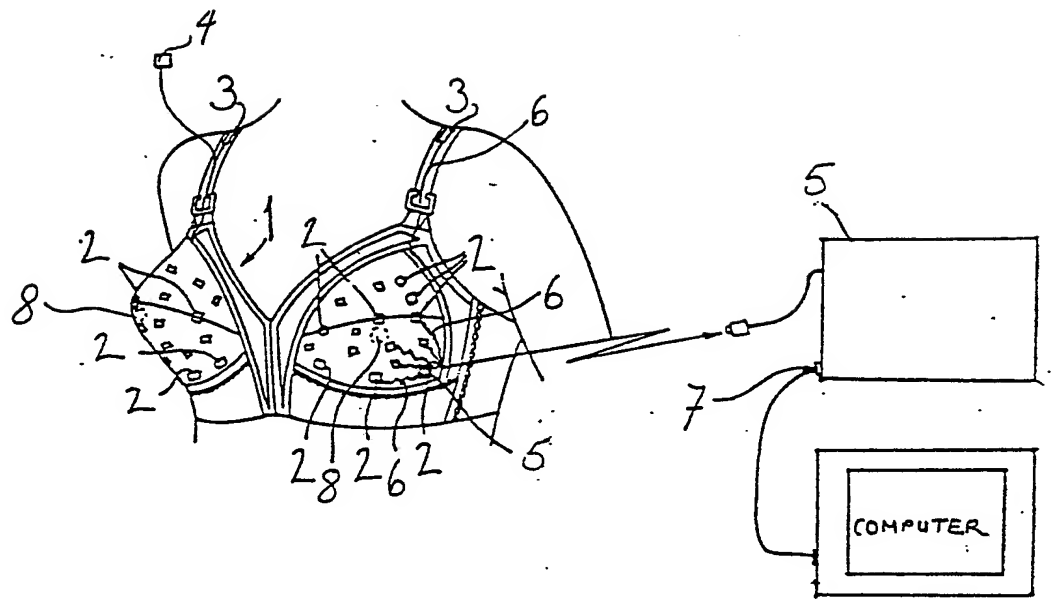


Fig. 1

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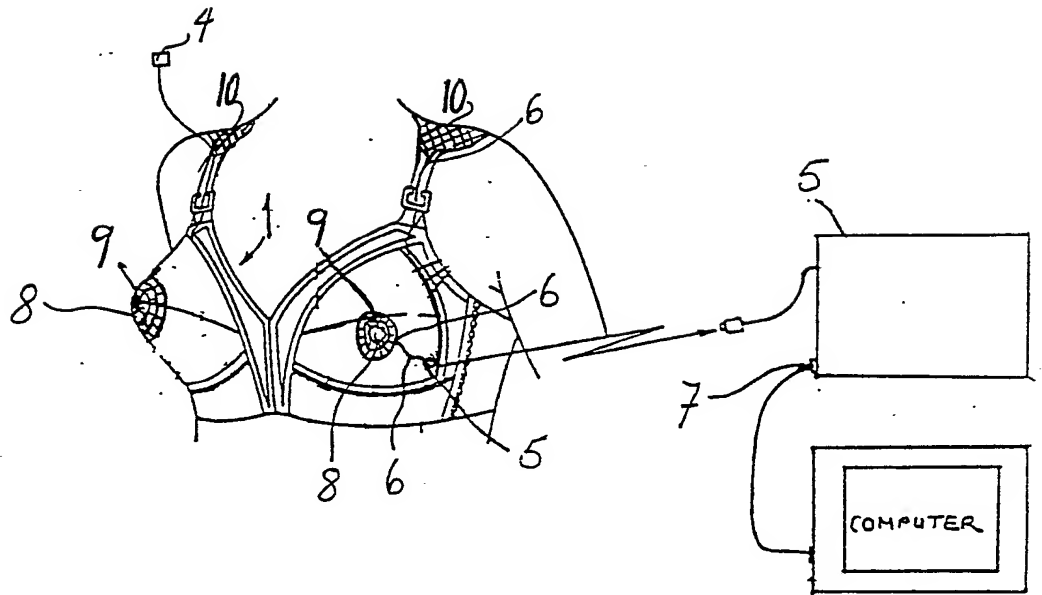


Fig. 2.

"Method of and Apparatus for Measurement of a Physical
Parameter of Body Tissue"

This invention relates to a method of and apparatus for measurement of a physical parameter of body tissue and is particularly, but not exclusively, for measurement of the surface temperature of the breast.

It has been known for many years that the surface temperature of the breast gives an indication of its metabolic state. For example, it has been shown that the normal breast is cooler than the axilla (armpit) whereas the pregnancy breast is the same and the lactating breast warmer than the axilla; moreover, with unilateral lactation there is unilateral hyperthermia. Indeed, the temperature of the breast may be indicative of a predisposition to cancer and certainly if drug therapy is to be used in any pre-emptive strategy for breast cancer, then it is important that as much information as possible is gathered on the effects of such drugs on the mammary gland, including its temperature rhythms which are largely the result of the menstrual rhythm, the circadian rhythm and other endogenous rhythms.

The importance of obtaining an error-free breast temperature rhythm is that abnormalities of this rhythm have been noted

in cancerous tissue and occurs both in the breast with cancer and in the other breast. The identification of women with abnormal signals in the general population would be of great value, because this could be used as the basis of so-called intervention therapy i.e. drugs which specifically dampen down, for example, the menstrual effects on the breast and hence presumably the risk of the final mutation towards cancer. Any device proposed for measuring breast temperature must be practical, harmless and comfortable as otherwise its use as a screening procedure would be limited. Additionally, if the breast temperature rhythm is to be measured appropriately in all women, then some sort of correction will be necessary in order to remove any environmental effects, such as ambient temperature and temperature increase due to body movement and the like.

According to the present invention there is provided a method of detecting body tissue which is susceptible to cancer comprising measuring the tissue specific temperature of the tissue, comparing said temperature with a previously established standard and quantifying said susceptibility from said comparison.

The method may comprise measuring the tissue specific temperature of the tissue, measuring body temperature, comparing the difference between the two temperatures with a previously established standard and quantifying the susceptibility from said comparison.

This method may include the measuring of tissue temperature from the nipple region only and averaging the temperature in this region to evaluate the tissue specific temperature.

The nipple region may comprise the nipple and breast tissue peripheral to the nipple extending for a few centimeters

from the nipple.

The method may include measuring body temperature at a number of points, which may include the highest point on the shoulder, the clavicle and the front muscles.

Further according to the present invention there is provided apparatus for determining a physical parameter of body tissue, comprising means for determining a tissue temperature, means for determining body temperature and means for determining ambient temperature, and determining from these a tissue specific temperature which is used to determine the susceptibility of said tissue to cancer.

Still further according to the present invention there is provided a garment for determining a physical parameter of a body tissue, comprising more than one sensor for measuring the surface temperature of said tissue, a sensor for measuring the surface temperature of the body and a sensor for measuring ambient temperature, and from these determining a tissue specific temperature, which is used to determine the susceptibility of said tissue to cancer.

Preferably, the apparatus is used to determine the temperature and temperature periodicity of breast tissue, these parameters being related to the likelihood of the development of breast cancer.

There may be a plurality of tissue temperature sensors in the cups of the garment or there may be a single sensing device centred on one region, such as the nipple and surrounding tissue.

The sensing device may comprise a net of high thermal conductivity wire centred on the nipple: the hot spots and

cold spots may be averaged out by conducting the temperature evenly throughout the net and monitoring at one point only.

The garment may be a brassiere or a tee-shirt, made from a fabric which can stretch in all directions and therefore accommodate various shapes of breast; the stretchiness also helps to keep the sensors in contact with the surface of the breast.

Preferably, the body temperature sensor is placed in a shoulder strap of the brassiere or tee-shirt.

There may be one sensor to each strap or there may be a plurality of sensors or a sensing device in the form of a net of high thermal conductivity wire, preferably extending from the clavicle to the highest point of the shoulder to the front muscle. The hot spots and cold spots may be averaged out by conducting temperatures evenly throughout the net and monitoring at one point only.

Preferably, an electronic microprocessor is included, and programmed to store, calculate and compute the information gathered by the sensors.

Preferably, there is data logging means external to the garment for providing a display of the information stored and calculated by the microprocessor.

Preferably, the garment includes a microprocessor, a plurality of sampling means and a timepiece means.

Preferably, the device is self powered and all wiring is integral to the garment; all wires may be slack to prevent being pulled taut when the garment is stretched.

An embodiment of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Fig. 1 is a perspective front view of one embodiment of the apparatus for use in determining a physical parameter of body tissue made in accordance with the present invention; and

Fig. 2 is a perspective front view of an alternative embodiment of the apparatus for use in determining a physical parameter of body tissue made in accordance with the present invention.

Referring to the Fig. 1 of the drawings, there is shown apparatus for use in determining a physical parameter of body tissue, the apparatus comprising a garment in the form of a brassiere 1, with a miniaturised electronic sixteen channel heat measuring device which has a number of cup temperature sensors 2, two shoulder temperature sensors 3, an ambient temperature sensor 4, which may be pinned to the lapel of outer clothing, and an electronic microprocessor 5. The device is self-powered.

The brassiere 1 is made from a fabric which can stretch in all directions without an undue increase in pressure on the breast; thus the brassiere 1 can accommodate various shapes of breast and keep the sensors in contact with the upper surface of the breast. A small hole 8 is provided in the inner fabric of the brassiere 1 and, by locating the nipple in the hole 8, a physician can ensure that the brassiere is correctly fitted.

Output signals from the sensors 2 are carried, by wires 6,

to the microprocessor 5. All wiring is integral to the garment and the wires 6 within the fabric of the brassiere 1 are provided with a degree of slack to prevent them being pulled taut when the brassiere 1 is stretched. The circuitry also includes a clock (not shown) and the sixteen thermometry channels that may be systematically sampled at intervals which may range from 64 seconds to longer than an hour. The data are stored in digital form in a memory store which is capable of retaining over 4,000 temperatures and, subsequently in a laboratory, the data may be transferred to an computer through a jackplug socket facility 7 of the microprocessor 5. The measurements are accurate to 0.05°C .

The apparatus is to measure the menstrual temperature variations and periodicity of the human breast, which may fluctuate in response to the menstrual cycle by to 1 to 3°C , from a low on day 15 to a high on about day 26 of a conventional 28 day menstrual cycle. Whereas some women show a very clear menstrual breast temperature rhythm, in others the rhythm is obscured by "noise". The "noise" correlates with the variations in the ambient temperature and also variations in the general body temperature which mirrors ambient effects but may also vary due to physiological reactions, for example, to movement and circadian rhythms. To obtain a breast specific temperature rhythm which may be measured appropriately from all women, a form of correction is necessary in order to remove the "noise" of environmental effects and certain endogenous rhythms.

The importance of obtaining a relatively error-free breast specific temperature rhythm is that the parameters of this rhythm may change in response to pre-emptive drug strategy for breast cancer, or the parameter may indicate breast pathology which, in turn, may be related to the risk of

breast cancer.

In use, the brassiere 1 is to be worn by a woman for example, for 1 to 1.5 hour span, at a set period each day or night for a full menstrual cycle of approximately 26 to 28 days. The menstrual cycle may be tracked by studying serial salivary progesterone concentrations. If the study is to find out the effects of pre-emptive drugs, a further 26 or 28 day study should be carried out after starting therapy. The measurements are taken during a set period of each day or night in order to mitigate the effects of the diurnal or nocturnal temperature rhythms of circadian and other endogenous rhythms. As the brassiere 1 is worn, the clock and microprocessor co-ordinate the taking of a series of measurements; the cup sensors 2 measure the surface temperature of the breast tissue, the shoulder sensors 3 measure the temperature of the body and the ambient sensor 4 measures the environmental temperature. The data is computed and stored by the microprocessor 5 to be read off in the laboratory and subsequently analysed.

Referring to Fig. 2 of the drawings, there is shown an alternative embodiment of the apparatus. The garment is still in the form of a brassiere 1, but the plurality of cup sensors 2 of Fig. 1 are replaced by a single sensor net 9 of high thermal conductivity wire centred on the nipple and extending laterally for a few centimeters around each nipple. In addition, the strap sensors of Fig. 1 are replaced by a shoulder sensor net 10, each of which extends from clavicle to high point of the shoulder and to the front muscles also. The net sensors 9, 10 average out the hot and cold spots of the underlying tissue by conducting temperature throughout the net and then monitoring at one point only per net. As for the apparatus of Fig. 1, the data is collected and stored by the microprocessors for

later computation and analysis.

The computations, either carried out by the microprocessor or back in the laboratory, are in order to calculate the breast specific temperature and the breast specific temperature rhythm. Ambient and general body temperature must be measured to correct the breast data and obtain a temperature and temperature rhythm which are relatively error-free. Fluctuations in environmental temperature may be of the order of 8°C in domestic circumstances, even where the occupant knows the temperature of the room and is attempting to control it. In turn, the range of variation in the body temperature taken, for example, at the shoulder, may fluctuate by 4°C and the breast temperature in turn might vary by 2°C . There is thus progressive damping of the environmental signal from the room temperature to the shoulder temperature to the breast temperature. A correction obtained by simply subtracting the shoulder or room temperature variation from the breast temperature is therefore inappropriate. A method of cross-correlation is required whereby the deviation from the mean temperature of the shoulder or ambient air is cross-correlated with the mean temperature deviation of the breast; the precise magnitude of the corrections for ambient fluctuations are determined in this way and the breast temperature data appropriately corrected.

In more detail, the corrections may be undertaken by, firstly, subtracting the menstrual periodicity from the breast data by fitting a cosine function, for example, of a period of 28 days, and "flattening" the menstrual trend. Secondly, the residual breast temperature series is averaged and each datum expressed as a deviation from the mean. The ambient temperature would be treated in the same way, that is the mean and the deviations from the mean would be

computed. The two sets of deviations, the ambient deviations and the residual breast temperature deviations, would then be cross-correlated and the breast temperature then corrected. Having obtained the corrected value the breast periodicity would then be re-introduced into the data to obtain the corrected menstrual rhythm.

The data obtained from the shoulder sensor 3 may also contain some useful environmental correction that is not due to the ambient temperature, but instead due to, for example, the movement of the patient and is therefore the periodicity of body temperature. To correct for this the ambient temperature deviations should be cross-correlated with the shoulder temperature deviations and the shoulder data corrected for the environmental fluctuations. The shoulder series have now have been corrected for the environment, but will still contain "physiological" corrections which can then be subtracted from the breast data, and thus a breast specific temperature rhythm may be obtained.

The breast specific temperature may be compared directly with an established standard to evaluate the susceptibility of the breast to cancer, or the difference between the breast specific temperature and the body temperature, as calculated from the measurements of shoulder sensors 3 or net sensor 10, may be calculated and the difference compared with an established standard in order to evaluate the susceptibility.

Other information may also be computed or taken into consideration by the microprocessors 5 of either embodiment of the apparatus. The other information may include; patient's deep body temperature (possibly measured by an oral sensor under the patient's tongue and usually assumed to be 37°C), age and breast size. The patient's age is

important as aging may alter the properties of the body tissue. Breast size must be taken into account as larger breasts, have lower surface temperatures, lower heat flow per unit area and higher resistance than smaller breasts.

The object of all the corrections is to produce the "purest" breast specific temperature and temperature rhythm which are free of ambient temperature variations and other physiological or environmental reactions.

The apparatus of the present invention may be for home use or for use in clinics where preventative medicine is practised. In such a clinic a brassiere 1 of the invention would be fitted by a physician and the woman instructed to sit in a room with controlled temperature environment until thermal equilibrium has been established. The time this takes is rather variable, and may be shortened by keeping the apparatus at 37°C before use. A container kept at 37°C may be provided for this purpose.

As a screening device, the apparatus and method provide means for a very early indication of the existence of cancer or of the likelihood of cancer developing, giving the possibility of preventative or pre-emptive intervention by the physician using known techniques.

It is envisaged that the apparatus may also be of use for those women who have so called "border-line" biopsies in which the pathologist has a particular problem of allocating a benign or malignant connotation to the lesion. Such cases could be monitored at regular intervals by the clinic in repeated follow-up examinations, to find out if any risk indices were increasing.

The apparatus may also be used for "high risk" women who,

for example, have had biopsies showing epitheliosis, and are undertaking a pre-emptive drug course. The effect of the drugs on the breast specific temperature and cycle may therefore be effectively monitored and, furthermore, the apparatus may identify those women that may benefit by a pre-emptive drugs strategy.

Modifications and improvements may be incorporated without departing from the scope of the invention.

CLAIMS

1. A method of detecting body tissue which is susceptible to cancer comprising measuring the tissue specific temperature of the tissue, comparing said temperature with a previously established standard and quantifying said susceptibility from said comparison.
2. A method as claimed in Claim 1 and including measuring body temperature, comparing the difference between the tissue specific temperature and said body temperature with a previously established standard and quantifying the susceptibility from said comparison.
3. A method as claimed in either preceding Claim and including measuring of tissue temperature from the nipple region only and averaging the temperature in this region to evaluate the tissue specific temperature.
4. A method as claimed in Claim 3, wherein the nipple region comprises the nipple and breast tissue peripheral to the nipple extending for a few centimeters from the nipple.
5. A method as claimed in any one of Claims 2 to 4 including measuring body temperature at a number of points, including the highest point on the shoulder, the clavicle and the front muscles.
6. Apparatus for determining a physical parameter of body tissue, comprising means for determining a tissue temperature, means for determining body temperature and means for determining ambient temperature, and means for determining from these a tissue specific temperature which is used to determine the susceptibility of said tissue to cancer.

7. Apparatus as claimed in Claim 6 including means for determining the temperature and temperature periodicity of breast tissue, these parameters being related to the likelihood of the development of breast cancer.

8. A garment for determining a physical parameter of a body tissue, comprising a number of sensors for measuring the surface temperature of said tissue, a sensor for measuring the surface temperature of the body and a sensor for measuring ambient temperature, and means for determining a tissue specific temperature to determine the susceptibility of said tissue to cancer.

9. A garment as claimed in Claim 8 and including a plurality of tissue temperature sensors in the cups of the garment.

10. A method of detecting body tissue which is susceptible to cancer substantially as hereinbefore described with reference to the accompanying drawings.

11. Apparatus for determining a physical parameter of body tissue substantially as hereinbefore described with reference to the accompanying drawings.

12. A garment for determining a physical parameter of a body tissue substantially as hereinbefore described with reference to the accompanying drawings.